CLAIMS

1. A method for the production of micropellets comprising one or more hard to dissolve effective agents, the method comprising producing micronized particles ~~are~~ of the effective agents from dispersions with functional adjuvants for the formation of a solid dispersion of the particles by spray granulation in a fluidized bed process, with the functional adjuvants and other components for the formation of the micropellets being provided in a dissolved or dispersed form.

2. A method according to claim 1, wherein a weight ratio of the functional adjuvants for formation of the solid dispersion to the effective agent ranges from 20:1 to 1:100.

3. A method according to claim 1, wherein the effective agent is provided in a micronized form with a grain size of 30 µm or less.

4. A method according to claim 1, wherein one or more solutizers are provided as the functional adjuvants for the formation of the solid dispersion, comprising one or more polyoxypropylene polyoxyethylene condensates, fatty acid polyglycol ether, alkyl phenol polyethylene glycolether, triglycerides, anionic tensides, cationic tensides, amphoteric detergents or non-ionic tensides, or a polyoxypropylene oxyethyelene (block)polymerisate.

5. A method according to claim 1, wherein one or more effective agents are provided as the hard to dissolve effective agents, selected from one or more of macrolide antibiotics, comprising azithromycin, antiviral therapeutics which are hard to dissolve in water, analgetics which are hard to dissolve in water, cardiovascular medications which are hard to dissolve in water, antiphlogistics which are hard to dissolve in water, and cancer therapeutics which are hard to dissolve in water.

6. A method according to claim 5, wherein clarithromycin is provided as the hard to dissolve effective agent.

7. A method according to claim 1, wherein the solid matter to be pelletized is provided as a liquid dispersion, comprising the micronized effective agent and the functional adjuvants for the formation of the solid dispersion and a desired binder, injected from a bottom into a fluidized bed arrangement which is empty at a beginning of the process;

starting seeds for pelletizing being formed by way of spray granulation of the dispersion without the presence of any other inert material; and

the micropellets produced during the process being sifted via a classification device, and being removed from the separator when reaching a predetermined pellet size.

8. A method for the production of a dispersion of a micronized effective agent, wherein

in a first separate step, a homogenous suspension of the micronized effective agent is produced in water, by suspending the micronized, hard to dissolve, not water-soluble effective agent, several respective effective agents or a respective mixture of effective agents using a powder-wetting or dispersing device and by a mixer for homogenizing and/or deaerating the dispersion in water under deaeration and homogenization;

in another separate step, mixing a solution of the soluble functional adjuvants and other components for the formation of micropellets is mixed in a solvent, until the solution becomes clear;

and mixing the dispersion of the first step and the homogenous solution of the other step with one another and deaerating in a subsequent step such that a homogenous liquid dispersion develops, advantageously using powder wetting or dispersing devices, with the homogenous solution being introduced by the device

and mixed with the dispersion containing the effective agent and the mixture and the deaeration being simultaneously carried out by a jet stream mixer.

9. A method according to claim 7, wherein the dispersion is nebulized in a fluidized bed evaporator, with the solvent being removed during a drying process through evaporation for the production of micropellets.

10. Micropellets produced according to the method according to claim 1.

11. A method according to claim 1 comprising the micropellets being produced with the following components:

(i) the pharmacological effective agent in a micronized form at a ratio from 10 through 99% by weight;

(ii) the functional adjuvants for the formation of a solid dispersion at a ratio from 1 through 90 % by weight and

(iii) a binder at a ratio from 0 to 20 % by weight.

12. A method according to claim 11, wherein the micropellets are produced having a diameter from 0.1 to 500 µm in spherical form.

13. Micropellets according to claim 11, wherein the micropellets are produced so that no more than 25 % by weight of the pellets have a diameter deviating by more than 25 % (+/-) from a mean diameter of all of the pellets.

14. A method according to claim 11, wherein the micropellets are produced having a pharmaceutical formulation.

15. A method for producing coated micropellets, comprising the production of a micropellet according to claim 1, wherein after the production of the pellets, a coating is also applied in a fluidized bed process, with nozzles in a base atomizing a

coating fluid, in which the coating agents are dissolved or emulgated, in a parallel flow into the micropellets to be coated.

16. A method according to claim 15, wherein after a first internal protective coating, subsequently one or more coatings are applied.

17. Coated micropellets, produced according to the method according to claim 15.

18. Coated micropellets according to claim 16, provided with two coatings, comprising an inner protective coating and an outer coating resistant to gastric juice.

19. Coated micropellets according to claim 17, wherein within 15 minutes the micropellets show a release in effective agent of 75 % or more in a US paddle test at 75 rpm in a solution with pH of 6.8 or higher.

20 A method according to claim 15, wherein the coated micropellet comprises a pharmaceutical formulation.